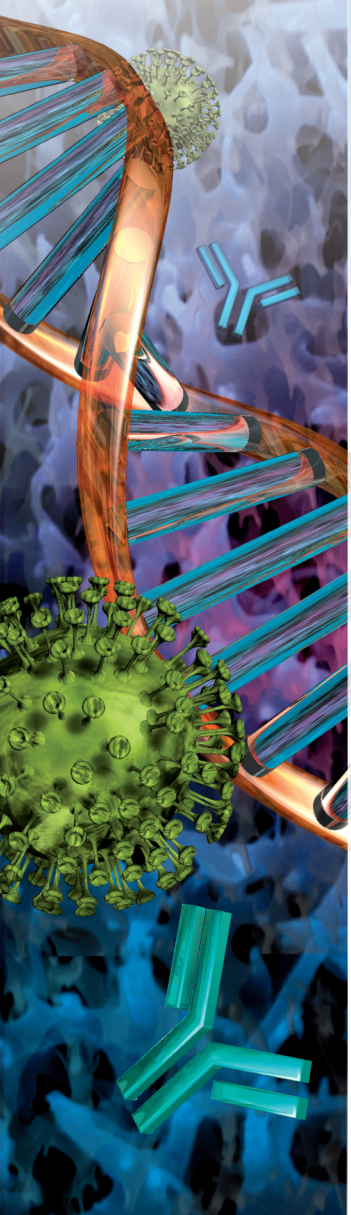
PALL Life Sciences

USD 2776

Resolute® FM Chromatography Columns



Advanced column design enabling true linear scale-up

Resolute FM columns are ideal for chromatographic purification from process development through to manufacturing scale with a wide range of commonly used media. These glass columns, for development and manufacturing applications, are robust and incorporate new features to improve the outcome of column packing events. The industry accepted constant compression seal design used in the successful Resolute DM range is also incorporated in the FM series. The columns are ideal for use with Pall's PKP chromatographic systems providing an ideally suited platform for pilot scale and small volume manufacturing purification operations with a wide range of chromatographic media. Accessory column valves and tubing kits are available to provide a complete solution for your next purification challenge.

Key Features and Benefits

- Unique constant compression adjuster seal simplifies column operation
- Low friction adjuster mechanism enables packing compression to x1.2cf
- Easy air removal prior to packing for first-time packing event
- Improved safety with an adjuster that enables packing without removal from column
- Low pressure drop flow path supports high linear velocity up to 700 cm/hr for maximum productivity
- Simple maintenance of seals and nets with quick and easy removal of both distributor plates without use of special tools
- Hygienic design suitable for effective sanitization
- Precision borosilicate glass tube and stainless steel flow path provides excellent chemical compatibility
- Scale up with 3 column sizes: 100, 140, and 200 mm diameter with capacities from 0.78 L to 8.4 L

*Filtration. Separation. Solution.*SM

Applications

The superior design of Pall's Resolute columns is optimized for purification in both process optimization and small scale manufacturing operations. These columns have proven performance with a wide range of chromatography media and chromatographic modes including: ion exchange, mixed mode, affinity, size exclusion and hydrophobic interaction. Column bed heights up to 27 cm may be prepared with a compression factor of 1.2.

Modular Design

Resolute FM columns can be packed and unpacked with the column adjuster remaining supported above the top of the tube. The central adjuster mechanism enables the top distribution cell to travel within the tube and to be raised clear of the tube for packing and unpacking operations. Thus eliminating the requirement to remove and lay down the adjuster and associated tubing. This improves operator safety and reduces preparation time with connected hoses being left in place.

The adjuster seal positioned close to the edge of the distribution plate is under constant compression within the tube. There is no need to adjust and fine tune seal compression as a seal is assured every time without operator involvement. This feature avoids problems associated with seals being either under or over compressed. This avoids leakage of fluids past the seal during the lowering of the adjuster during axial bed compression.

Unlike other column designs, the adjuster is always maintained in a relative vertical plane to the column tube by the adjuster plate and does not need to be inserted by the operator at an angle into the tube to remove air while the seal is formed against the tube wall. Resolute FM columns have a unique feature on the lower frame which allows the column assembly to be tilted from vertical while the adjuster is lowered. This feature has simplified the packing preparation process and results in a reproducible outcome which can be defined in SOP's and avoids awkward handling of heavy column components and attached tubing. This procedure is ideal for concise SOP's and produces reproducible column priming outcomes due the security of the mechanical steps involved in place of manual manipulation of separate column parts.

Fast Packing and Unpacking

The design of the central adjuster mechanism provides adequate clearance for entry of the slurry directly into the column tube. With a measured volume of slurry in the column, the liquid level is then topped up with buffer to a specific bed height (marked on the tube unit). The column is then set in the priming position and the adjuster lowered into the tube by rotating the centrally located handles. As the seals enter the tube the air is displaced, and once the seal is made the column is again set vertical before applying the required flow to pack the bed. Once the bed is compressed to a target value the flow is stopped and the adjuster lowered to meet the packed bed. This may be repeated several times dependant on media type.

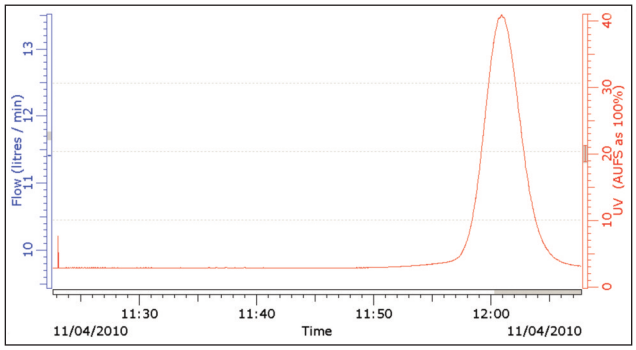
Unpacking can be performed through the bottom or top of the tube. Typically, the adjuster is raised by rotating the centrally located handles until it is clear of the tube. After rinsing the top distribution plate and net to recover residual media, the column contents are gently agitated with buffer to form a slurry before being pumped to a container.

Performance

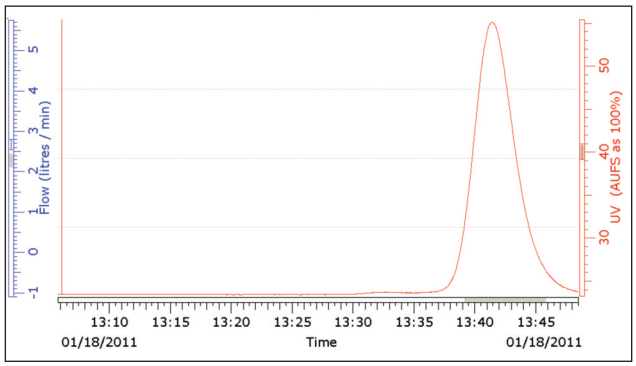
Figure 1

Acetone 2% (w/v), injection volume 1 - 5% Column Volume, bed height 20 cm.

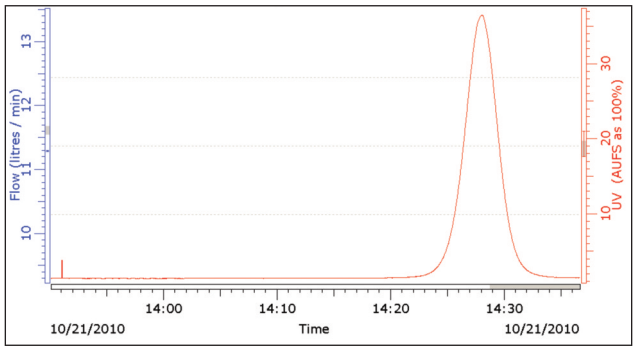
FM100



FM140



FM200



Ease of Use

Resolute FM columns are suitable for sanitization as an empty column (or in a packed condition), as well as having easy access to all seals and supports for fast maintenance requirements. With a minimal number of parts, access for wipe down and the electropolished stainless steel surface finish minimizes entrapment of contaminants and reduces the risk of corrosion. Validation of all column sizes demonstrated that the columns can be effectively sanitized.

Specifications

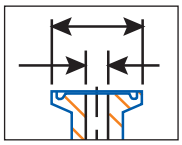
Product	Diameter (mm)	CSA (cm²)	Adjustable Height Range (mm)	Adjustable Capacity Packed Volume (L)*	Maximum Allowable Pressure (barg/psig)	Net Weight Kg (lb)	Column Height at Minimum Bed (mm)	Width (mm)	Depth (mm)	Height (mm)
Resolute FM	100	79	100 - 460	0.78 - 2.1	5.0/72.5	30/66	1105	385	385	1625
Resolute FM	140	154	100 - 460	1.54 - 4.1	5.0/72.5	45/99	1135	415	415	1655
Resolute FM	200	314	100 - 460	3.14 - 8.4	4.6/66.7	70/154	1135	455	455	1655

*Based on 70% slurry and compression factor x 1.2

Temperature
2 - 35 °C

Column Termination Sizes

	T1 mm	T2 mm
Diameter (mm) 100	4	25
Diameter (mm) 140	6	25
Diameter (mm) 200	6	25



Component Weights Kg (lb)

	FM100	FM140	FM200
Column	30 (66.1)	46 (101.4)	62 (136.7)
Adjuster Assembly Complete	8.6 (19.0)	18.57 (41.0)	25.1 (55.3)
Adjuster Distribution Plate Only	1.1 (2.4)	2.2 (4.8)	4.6 (10.1)
Fixed Distribution Plate Only	4.0 (8.8)	6.7 (14.8)	11.9 (26.2)

Materials of Construction
Process Wetted Components
Glass, borosilicate 3.3; Stainless steel, grade 316 L (EN 1.4404)
Nets: 20 µm – Polypropylene 10 µm – Polyamide
Net Support: Polypropylene

Seals
EPDM, black, peroxide cured

Stand
Stainless steel, grade 316 L (EN 1.4404)

Castors
Stainless steel, grade 304

External Components
Column Tube
Glass, borosilicate 3.3

Pressure Envelope Components
Stainless steel, grade 316 L (EN 1.4404)

Stand
Stainless steel, grade 316 L (EN 1.4404)

Castors
Stainless steel, grade 304

Wheels
Acetal

Materials used in the manufacture of the column product contacting components either conform to relevant sections of the FDA Code of Federal Regulations Volume 21, parts 170 to 199, or are non-FDA recognized materials that pass USP Class VI tests for toxicity. All Wetted Elastomers Conform to USP VI or CFR 177.2600.

Applicable Codes and Standards

Design Standard: Steel Components/Glass Tube	PD5500 (2009)/BSEN1595 (1997)
Mechanical Design	PED 97/23/EC
P.E.D. Category	SEP

Chemical Combatibility

Substance	Concentration	Stainless Steel	Polypropylene	EPDM	Glass	Column Overall Status	Nylon
Acetic acid	≤ 25%	✓	✓	✓	✓	✓	X
Acetone	50%	✓	✓	✓	✓	✓	✓
Acetonitrile	100%	✓	Softens after 7 days constant contact; effect is reversible	✓	✓	~	✓
Ammonium sulphate	2M	Minor corrosion to 304 stainless steel. Non-corrosive to 316.	✓	✓	✓	~	✓
Benzyl alcohol	2%	✓	✓	✓	✓	✓	X
Ethanol	100%	✓	✓	✓	✓	✓	✓
Ethanol	40%	✓	✓	✓	✓	✓	✓
Ethanol	20%	✓	✓	✓	✓	✓	✓
Ethyl acetate	100%	✓	✓	✓	✓	✓	✓
Ethylene glycol	50%	✓	✓	✓	✓	✓	✓
Formaldehyde	40%	✓	✓	✓	✓	✓	~
Formic acid	100%	✓	✓	✓	✓	✓	X
Guanidine hydrochloride	8M	X	✓	✓	✓	X	
Hydrochloric acid	20%	X	✓	✓	✓	X	X
Hydrogen peroxide	10%	✓	✓	✓	✓	✓	X
Isopropyl alcohol (IPA, Propan-2-ol)	100%	✓	✓	✓	✓	✓	X
Nitric acid	5%	✓	✓	✓	✓	✓	X
Nitric acid	20%	✓	✓	✓	✓	✓	X
Phosphoric acid	40%	Not recommended	✓	Minor effect	✓	✓	X
Sodium acetate	All conc.'s	✓	✓	✓	✓	✓	~
Sodium bicarbonate	All conc.'s	✓	✓	✓	✓	✓	✓
Sodium chloride	0.5M	At pH < 7 pitting occurs also on storage at any pH > 30 days	✓	✓	✓	~	✓
Sodium chloride	2M	At pH < 7 pitting occurs also at storage at any pH > 24 hrs	✓	✓	✓	~	✓
Sodium hydroxide	2M	✓	✓	✓	Exposure > 3 months can damage glass surface	~	~
Sodium hydroxide	0.02M	✓	✓	✓	✓	✓	✓
Sodium hypochlorite	20% (200 ppm Cl)	Some discoloration can occur if contact time is > 1 hr	Minor effect	Minor effect	✓	~	X
Sodium nitrate	All conc.'s	✓	✓	✓	✓	✓	✓
Sulphuric acid	≤ 10%	Some minor effect	✓	✓	✓	✓	X
Tri-n-butyl phosphate with 1% Tween	≤ 3%	✓	✓	✓	✓	~	
Trifluoroacetic acid	≤ 0.1%	Higher concentration's can cause minor damage to steel	✓	✓	✓	~	
Triton X-100	3%+	✓	✓	✓	✓	✓	
Urea	8M	✓	✓	✓	✓	✓	✓

✓ Compatible
~ Limited compatibility
X Not compatible

Ordering Information

Resolute FM Chromatography Column

Item Description	Diameter (mm)	CSA (cm^2)	Adjustable Height (mm)	Adjustable Capacity Liters	Pressure psi	Pressure bar	Adjustable Capacity Columns: Resolute FM	Adjustable Capacity Columns: Resolute FM and Documentation Pack
FM 100/100-460	100	79	100 - 460	0.78 - 2.1	72	5	FM100A100A20	FM100A100A20D
FM 140/100-460	140	154	100 - 460	1.54 - 4.1	72	5	FM140A100A20	FM140A100A20D
FM 200/100-460	200	314	100 - 460	3.14 - 8.4	69	4.6	FM200A100A20	FM200A100A20D

NOTES: Column ships with 20 µm nets fitted.

Spares Kits and Accessories

	Spare Kits					
Column Ø (mm)	Fixed & Adjuster Net (10 µm)	Fixed & Adjuster Net (20 µm)	Adjuster Net Support	Fixed Net Support[1]	Wetted Seals[2]	Non Wetted Seals[3]
100	SFM100A150A99	SFM100A160A99	SFM100A350A99	SFM100A360A99	SFM100A300A99	SFM100A340A99
140	SFM140A150A99	SFM140A160A99	SFM140A350A99	SFM140A360A99	SFM140A300A99	SFM140A340A99
200	SFM200A150A99	SFM200A160A99	SFM200A350A99	SFM200A360A99	SFM200A300A99	SFM200A340A99

Accessories

	Accessories				Tools	
Column Ø (mm)	Column Valve Kit[4]	Bottom Valve Mounting Kit[5]	Foot Kit	Tubing Kit[6]	Deep Socket[7]	Stirring Paddle
100	SFM100A270A99	SFM100A320A99	SFM100A310A99	SFM100A420A99	SFM100A330A99	SFM100A390A99
140	SFM140A270A99	SFM140A320A99	SFM100A310A99	SFM140A420A99	SFM140A330A99	SFM100A390A99
200	SFM140A270A99	SFM140A320A99	SFM100A310A99	SFM140A420A99	SFM140A330A99	SFM100A390A99

1. Net support (1) to fit between net and distributor
2. Adjuster seal (1), tube seal (2) , inlet tube seal (1)
3. Adjuster nut flange seal (1), inlet spool top seals (2)
4. Two way valve (1), clamp (1), gasket (1) [2 valve kits required per column for top and bottom]
5. Bottom elbow (1), clamp and gasket (1), bracket (1) and bolts/washers (2)
6. Reinforced tubing (2 x 150 cm, 1 x 200 cm) with hose barbs (6), gaskets (6) and clamps (6)
7. Required when dismantling tube assembly

Documentation

- Each column is supplied with a user manual
- CD-ROM with user manual and language versions

Installation and Validation Documentation

Resolute FM columns can be ordered with an optional** comprehensive validation and support package. To support validation efforts and efficient commissioning, this documentation includes all the pre-shipment test results.

- Column documentation includes:
  - Setup and test report
  - Materials and compatibility data
  - Comprehensive parts list

**Must be ordered with column at time of purchase

Chromatography Process Solutions from Pall

Pall offers a comprehensive, versatile and environmentally friendly range of chromatography sorbents that greatly simplifies protein purification challenges from lab to process scale. Pall chromatography sorbents can improve the downstream purification accuracy, speed, safety, reliability, and decrease purification cost. Sorbent chemistries include ion exchange, mixed mode, hydroxyapatite, affinity, size exclusion, solvent-detergent removal and HIC.

The PK solution platform and PKP chromatography system range incorporate proven component technology, delivering accurate precision gradients as well as in-line buffer dilution. This occurs while maintaining the performance necessary to make your chromatography process consistent from batch-to-batch and optimal at pilot and manufacturing scales. Covering a range from 1 - 4000 L/h, Pall's PK and PKP systems ensure robust operation and flexibility for all biochromatography applications. These systems can be used with Resolute chromatography columns as well as Mustang® chromatography membrane adsorber capsules.

PKP Chromatography System

Pall LRC chromatography columns have been designed to meet the requirements of most laboratory applications (ion exchange, affinity, size exclusion, mixed-mode chromatography). Four internal diameters, from 10 to 50 mm, and four lengths provide a range of column volumes up to 900 mL and bed heights up to 750 mm. Each column is supplied assembled and ready-to-use with tubing and fittings for connection to a standard system. The column body is made of a borosilicate glass tube. The columns are equipped with one adjustable and one fixed plunger, and a screw-lock system, to allow a rapid adjustment of the piston.

LRC Glass Columns

The Resolute DM columns are equipped with Pall's proprietary high resolution mobile phase flow path, which consists of a mobile phase flow path within the nozzle valve body, distribution end cells, and a fully flushed piston seal arrangement. The performance of these essential column components is increasingly important for optimal process efficiency, capacity, and peak symmetry when scaling up to larger capacity columns.

Resolute DM columns maintain identical design parameters throughout both the standard column range (from 280 mm to 1200 mm diameter) and the larger capacity columns (up to 2000 mm diameter). Operation at high linear velocities is free from non-linear column effects and assures true linear scalability of column performance, enabling users to scale up simply without method redevelopment or impact on the reproducibility of the packing process.

Resolute Column

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